IS 16097 : 2013

(Reaffirmed 2018)

भारतीय मानक

निजीवाणुक एक बार उपयोग स्केल्प वेन (विंगदार सुई) इनफयूजन सेट

Indian Standard

STERILE SINGLE USE SCALP VEIN (WINGED NEEDLE) INFUSION SET

ICS 11.040.20

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BUREAU OF INDIAN STANDARDS
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NEW DELHI 110002

August 2013 **Price Group 3**

Surgical Disposables and Dressings Products Sectional Committee, MHD 16

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the finalized by the Surgical Disposables and Dressings Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard covers sterile scalp vein (Winged needle) infusion set intended for single use primarily in humans. It does not give requirements or test method for freedom from biological hazards because international agreement upon the methodology and the pass/fail criteria is incomplete. Guidance on biological evaluation and tests are given in IS12572 (Part 1):1994/ISO10993-1: 1992 ‘Biological evaluation of medical devices : Part 1 Guidance on selection of tests (*first revision*)’ and it is suggested that manufactures take this guidance into account when evaluating products. Such an evaluation should include the effects of the process whereby the infusion sets are sterilized. However, national regulations may exist in some countries, and these will override the guidance in IS 12572 (Part 1) : 1994/ ISO 10993-1:1992.

Plastic materials to be used for the construction of scalp vein infusion set are not specified, as their selection shall depend to some extent upon the design, process of manufcture and method of sterilization employed by individual manufacturers. The materials should be compatible with injection fluids (*see* IS 10654 : 2002 ‘Sterile hypodermic needles for single use’).

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, oserved or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 ‘Rules for rounding off numerical values (*revised*)’. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

STERILE SINGLE USE
SCALP VEIN (WINGED NEEDLE) INFUSION SET

1 SCOPE

This standard specifies requirement for scalp vein infusion set supplied in the sterile condition and intended for single use.

2 REFERENCES

The following standards contain provisions, which, through reference in this text, constitute provision of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below:

IS No./ International Standard	*Title*
3234 (Part 1) : 1986/ISO 594-1 : 1986	Conical fitting with 6 percent (luer) taper for syringes, needle and certain other medical equipment: Part 1 General requirement.
10654 : 2002/ ISO 7864 : 1993	Sterile hypodermic needle for single use
ISO 9626 : 1991	Stainless steel needle tubing for the manufacture of medical devices

3 NOMENCLATURE

The nomenclature for components of scalp vein infusion set for single use is shown in Fig. 1. Nomenclature for needle point is shown in Fig. 2.

4 CLEANLINESS

4.1 When inspected by normal or corrected to normal vision without magnification the surface of the Infusion set shall appear free from particle and extraneous matter.

4.2 When examined under X 2.5 magnification the adopter socket shall appear free from particle and extraneous matter (*see* IS 10654).

5 LIMITS FOR ACIDITY AND ALKALINITY

When determined with a laboratory *p*H meter and using a general purpose electrode, the *p*H value of an extract prepared in accordance with Annex A shall be within one unit of *p*H of that of the control fluid.

6 LIMITS FOR EXTRACTABLE METALS

When tested by a recognized micro-analytical method, for example by an atomic absorption method, an extract prepared in accordance with Annex A shall, when corrected for the metals content of the control fluid, contain not greater than a combined total of 5 mg/l of lead, tin, zinc and iron. The cadmium content of the extract shall, when corrected for the cadmium content of the control fluid, be lower than 0.1 mg/1 (*see* IS 10654).

7 SIZE DESIGNATION

7.1 The size of infusion set shall be designated by the following:

a) Nominal outside diameter of the needle tube expressed, in millimetres; and
b) Nominal length of the needle tube, expressed, in millimetres.

7.2 The size shall be referred to as the designated metric size and shall be expressed in millimetres.

Example: 0.8 × 40 (*see* IS 10654)

8 COLOUR CODING

The nominal outside diameter of needle tube shall be identified by colour coding. The colour coding can be applied to the unit container and/or part of the infusion set such as the wing or the sheath.

9 ADAPTER

The conical socket of the adapter shall be in accordance with IS 3234 (Part 1).

10 WING

Wing shall be made either of pigmented or unpigmented material, if pigmented, the colour shall be in accordance with Table 1.

11 SHEATH

A separate needle sheath shall be provided, it shall be made either of pigmented or of unpigmented material, if pigmented, the colour shall be in accordance with Table 1.

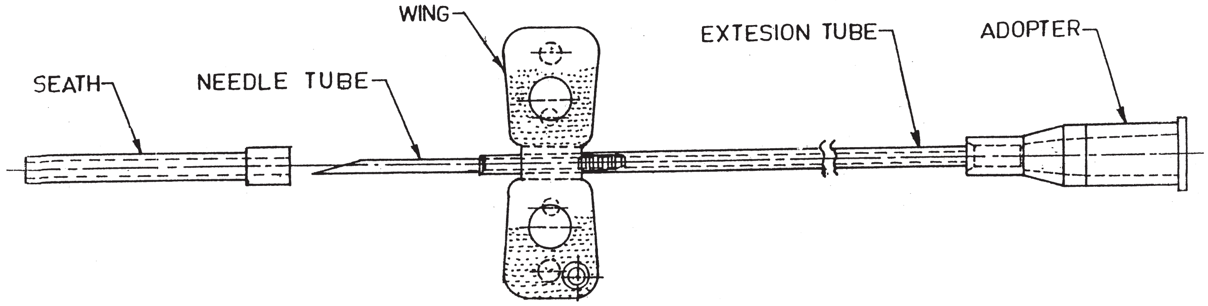
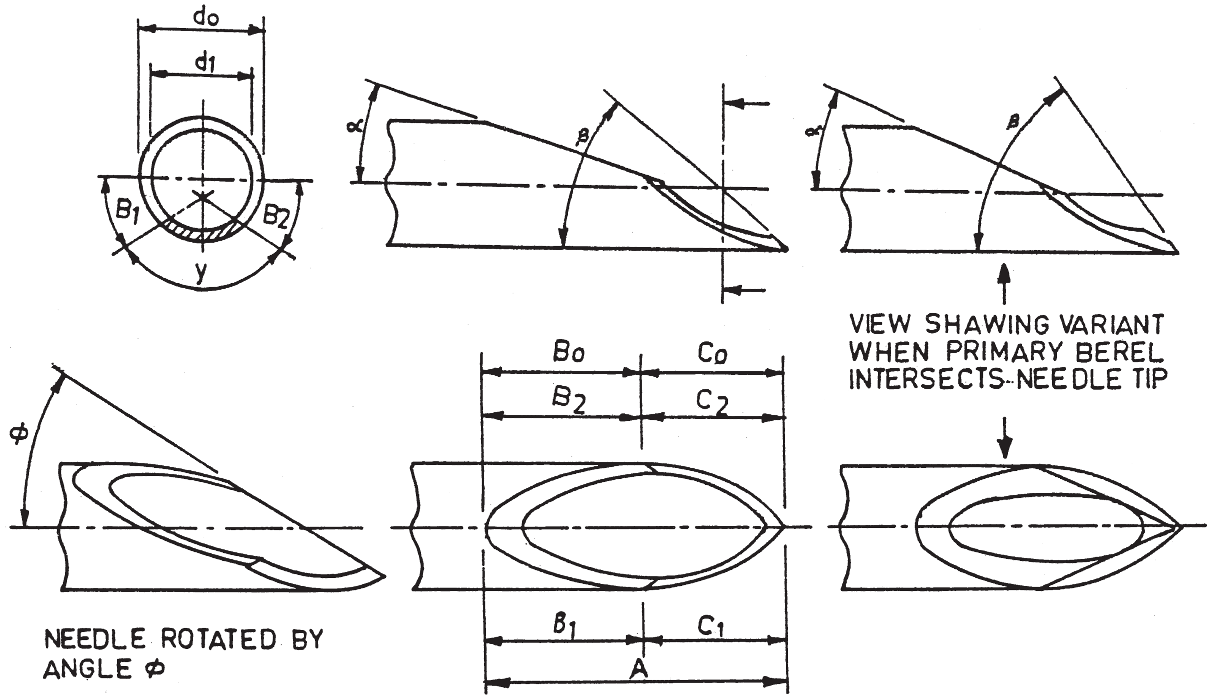


Fig 1 Example of Typical Scalp Vein Infusion Set


do
d1
B1
B2
y
α
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Co
B2
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C1
A
φ
VIEW SHAWING VARIANT WHEN PRIMARY BEREL INTERSECTS-NEEDLE TIP
NEEDLE ROTATED BY ANGLE φ

Key

d_0	Outside diameter of needle tube	C_2	Left secondary bevel length
d_1	Inside diameter of needle tube	α	Primary bevel angle
A	Point length	ϕ	Secondary bevel angle
B_0	Primary bevel nominal Length $B_6 = (A - C_0)$	β	Tip angle
B_1	Right primary bevel length	β_1	Right secondary bevel rotation angle
B_2	Left primary bevel length	β_2	Left secondary bevel rotation angle
C_0	Secondary bevel nominal length	γ	Combined secondary bevel angle

Fig. 2 Designation of Dimensions and Nomenclature of Needle Point Geometry

Table 1 Colour of Wing and Sheath

(*Clauses* 10 *and* 11)

Sl No. (1)	Nominal O.D of Needle (2)	Colour (3)
i)	0.4	Medium grey
ii)	0.45	Brown
iii)	0.5	Orange
iv)	0.55	Purple
v)	0.6	Blue
vi)	0.7	Black
vii)	0.8	Green
viii)	0.9	Yellow
ix)	1.1	Cream
x)	1.2	Pink
xi)	1.4	Red violet

12 EXTENTION TUBE

Extension tube shall be made of flexible material. Tolerance on legth of the tube shall be ±5 percent (over the length specified by the manufacturer).

13 NEEDLE TUBE

The needle shall be made of tubing in accordance with ISO 9626.

13.1 Needle Length

Preferred needle length may be 19 mm (¾"), However manufacturer can vary the length to suit specific requirements. A general tolerance on specified length (up to 25 mm) shall be $^{+1}_{-2}$ mm .

13.2 Freedom From Defects

When examined by normal or corrected vision the needle tube shall appear straight and have regular cross-section and wall thickness (*see* IS 10654).

13.3 Lubrication

If the needle tube is lubricated, the lubricant shall not be visible under normal or corrected vision as droplets of fluid on the outside or inside surfaces of the needle tube (*see* IS 10654).

NOTE — An acceptable lubricant, is polydimethylsiloxane complying with a national or European pharmacopoeia.

14 NEEDLE POINT

14.1 When examined under X2.5 magnification the needle point shall appear sharp and free from feather edges, burrs, and hooks (*see* IS 10654).

14.2 The designation of needle point dimensions and the nomenclature used to describe the dimensions and features shown for information in Fig. 2. The needle points shown are of configurations commonly manufactured: other configurations may be equally satisfactory. It may not be necessary to use all the dimensions when describing the point configuration.

15 PERFORMANCE

15.1 Bond Between Wing and Needle Tube

The union of the wing and needle tube shall not be broken by the minimum force give below when applied for 15 s:

a) 10 N, when testing needle of nominal outside diameter less than 0.6 mm; and
b) 15 N, when testing needle of nominal outside diameter 0.6 mm or greater.

15.2 Bond Between Wing and Extention Tube

The union between wing and extension tube shall not be loosened when a force of 15 N is applied in pulling direction for 15 s.

15.3 Bond Between Extension Tube and Adapter

The union between adapter and extension tube shall not be loosened when a force of 15 N is applied in pulling direction for 15 s.

16 PACKING

16.1 *Primary Container*

16.1.1 Each infusion set shall be sealed in primary container. The material and design of this container shall be such as to ensure that the colour coding of the contents is visible.

16.1.2 The material of the container should not have detrimental effects on the contents. The materials and design of this container should be such as to ensure,

a) the maintenance of sterility of the contents under dry, clean and adequately ventilated storage conditions;
b) the minimum risk of contamination of the contents during removal from the container;
c) adequate protection of the contents during normal handling, transit and storage; and
d) that once opened, the container cannot be easily resealed, and it should be obvious that the container has been opened (*see* IS 10654).

16.2 Secondary Container

One or more primary containers shall be packaged in a secondary container. The secondary container should be sufficiently robust to protect the contents during handling, transit and storage. One or more secondary containers may be packaged in storage and/ or a transit container (*see* IS 10654).

17 LABELLING

17.1 Primary Container

The primary container shall be marked with at least the following information:

a) description of the contents, including the designated metric size in accordance with **7**;
b) Word 'STERILE';
c) Lot number, prefixed by the word 'LOT'; and
d) Name or trade-mark or trade-name or logo of the manufacturer or the supplier.

17.2 Secondary Container

The secondary container shall be marked with at least the following information:

a) A description of the contents, including the designated metric size in accordance with **7** and the number;
b) Word 'STERILE';
c) Words 'FOR SINGLE USE' or equivalent (excepting the term 'Disposable');
d) Warning to check the integrity of each primary container before use;
e) Lot number, prefixed by the word 'LOT';
f) Date of sterilization (month and year);
g) Name and address of the manufacturer or supplier; and
h) Information for handling; storage and transportation.

NOTE — The date of sterilization may be incorporated in the first several digits of the lot number.

17.3 Storage Containers

If secondary containers are packed in a storage container, the storage container shall be marked with at least the following information:

a) A description of the contents, including the designated metric size in accordance with **7** and the number;
b) Lot number, prefixed by the work 'LOT';
c) Word 'STERILE';
d) Date of sterilization;
e) Name and address of the manufacturer or supplier; and
f) Information for handling, storage and transportation of the contents.

18 BIS CERTIFICATION MARKING

The product may also be marked with the Standard Mark

18.1 The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act*, 1986 and the Rules and Regulations made thereunder. The details of conditions, under which the license for the use of Standard Mark may be granted to manufactures or producers, may be obtained from the Bureau of Indian Standards.

ANNEX A

(*Clause* 5)

METHOD FOR PREPARATION OF EXTRACTS

A-1 PRINCIPLE

The infusion set is immersed in water in order to extract soluble components.

A-2 APPARATUS AND REAGENTS

A-2.1 Freshly Prepared Distilled or Deionized Water, of Grade 3 in accordance with ISO 3696.

A-2.2 Selection of Laboratory Borosilicate Glassware

A-3 PROCEDURE

A-3.1 Immerse 05 Infusion sets in 250 ml of water (*see* **A-2.1**) in a suitable container made from borosilicate glass (*see* **A-2.2**).

Ensure that all surfaces of the infusion sets, including the inside of the surfaces of the needle tube, are in contact with the water. Maintain the water at a temperature of 37 + 3°C for 60 ± 2 min. Remove the infusion sets and ensure that all water from the inside and outside surfaces of the infusion sets is returned to the container.

A-3.2 Prepare the control fluid by following the procedure given in **A-3.1** but omitting the infusion sets.

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Amendments Issued Since Publication

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